AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listing of claims in the application:

Listing of Claims:

Claims 1-35 (Canceled)

36. (New) A method of producing particles from a feedstock material that comprises at least one therapeutic substance, prophylactic substance, diagnostic substance and/or excipient, for the use in the delivery of drugs to a selected drug delivery target region by inhalation, whereby at least one particle attribute, selected from the group consisting of morphology, topography or aerodynamic diameter, is engineered to provide particles with the aerodynamics necessary to become deposited at the selected drug delivery target region of a patient type with a known inhalation power, said method comprising the steps of:

a) providing a mimicked respiratory system, which is adapted to simulate at least one of the drug delivery target regions of the mammalian respiratory system;

b) providing an engineering medium within the mimicked respiratory system at a controlled temperature to create an environment that is conducive to the production of engineered particles, said medium comprising at least one gas;

c) operating the mimicked respiratory system to simulate a controlled inhalation flow rate within the system for a set period of time, whereby the controlled inhalation power imparted on the mimicked respiratory system is equal to

or greater than the inhalation power of the known patient type;

d) providing an aerosolized feedstock material within the mimicked respiratory system, whereby the type of engineered particles produced in the reaction of the feedstock material with the engineering medium is dictated by the controlled inhalation power;

e) collecting the resultant engineered particles from a simulated drug delivery target region, provided by the mimicked respiratory system, that corresponds to the selected drug delivery target region.

37. The method of claim 36, wherein the mimicked respiratory system is provided by a modified twin stage impinger, an Andersen cascade impactor, or any other device capable of simulating at least one drug delivery target region of the mammalian respiratory system.

38. The method of claim 36, wherein the drug delivery target regions simulated by the mimicked respiratory system are selected from the group consisting of naso-pharynx; oropharynx; trachea; bronchi; bronchioles; alveolar ducts; and alveolar sacs.

39. The method of claim 36, wherein the inhalation flow rate within the mimicked respiratory system is between 1 and 1000L/min.

40. The method of claim 36, wherein the inhalation flow rate within the mimicked respiratory system is set at a rate

which simulates a natural inhalation flow rate of a mammalian lung, which is between 15 and 120L/min.

41. The method of claim 36, wherein the feedstock material comprises at least one of the following constituents:

i) a therapeutic, prophylactic, or diagnostic substance;

ii) a liquid;

iii) an excipient; and

iv) a base and/or an acid.

42. The method of claim 36, wherein the feedstock material is sprayed into the mimicked respiratory system to provide the aerosolized feedstock material within the mimicked respiratory system.

43. The method of claim 36, wherein the feedstock material is sucked into the mimicked respiratory system to provide the aerosolized feedstock material within the mimicked respiratory system.

44. The method of claim 43, wherein the inhalation flow rate within the mimicked respiratory system provides the suction to draw the feedstock material into the mimicked respiratory system.

45. The method of claim 36, wherein the feedstock material comprises at least one therapeutic substance selected

from the group consisting of corticosteroids; anti-inflammatories; anti-tussives; bronchodilators; and proteins.

46. The method of claim 36, wherein the feedstock material comprises at least one therapeutic substance selected from the group consisting of beclomethasone diproprionate; budesonide; fluticasone propionate; salmeterol xinofoate; salbutamol sulphate; and bovine serum albumin.

47. The method of claim 36, wherein the feedstock material comprises at least one excipient selected from the group consisting of monosaccharides; disaccharides; polysaccharides; and sugar alcohols.

48. The method of claim 36, wherein the feedstock material is passed through a filter before entering the mimicked respiratory system to control the size of the aerosolized feedstock material particles.

49. The method of claim 48, wherein the feedstock material is filtered to permit only particles having a diameter of 100μm or less to enter the mimicked respiratory system.

50. The method of claim 36, comprising the further step of pre-treating the feedstock before it is introduced into the mimicked respiratory system.

51. The method of claim 50, wherein the pre-treatment step involves subjecting the feedstock to at least one liquefied gas.

52. The method of claim 36, wherein the engineering medium further comprises at least one fluid selected from the group consisting of water; a ketone; an alcohol; a fluorocarbon; a fluoroalkane; an acid; a base; a liquefied gas; and combinations thereof.

53. The method of claim 52, wherein the at least one fluid is selected from the group consisting of water; acetone; ethanol; hydrofluoroalkanes; chlorofluorocarbons; and liquid nitrogen.

54. The method of claim 52, wherein the step of providing an environment within the mimicked respiratory system further comprises agitating the engineering medium by directing the controlled inhalation flow through the at least one liquid present in the mimicked respiratory system.

55. The method of claim 36 wherein the inhalation flow gas is selected from the group consisting of air; nitrogen; oxygen; carbon dioxide; helium; argon; and combinations thereof.

56. The method of claim 36, wherein the temperature in the mimicked respiratory system is controlled at a temperature of between -200 and 200°C.

57. The method of claim 36, wherein the temperature is maintained at between -50 and 120°C.

58. The method of claim 36, wherein the temperature is maintained at a level which simulates that of the mammalian lungs, which is between 34 and 42°C.

59. The method of claim 36, wherein the engineering medium contains at least one effervescent substance.

60. The method of any of claim 36, wherein the feedstock material contains at least one effervescent substance.

61. The method of any of claim 59, wherein carbon dioxide is evolved by the combination of a base and an acid in an effervescent reaction.

62. The method of claim 36, wherein the mimicked respiratory system further comprises at least one spacer device.

63. The method of claim 62, wherein the at least one spacer device is provided in the mimicked respiratory system at a point between where the feedstock material is introduced into the mimicked respiratory system and the point where at least one of the simulated drug delivery target regions are provided by the mimicked respiratory system.

64. The method of claim 62, further comprising the step of creating a local environment within each spacer device that is distinct from that within the rest of the mimicked respiratory system.

65. The method of claim 62, wherein each provided spacer device comprises at least one inlet and at least one outlet, whereby the introduction of an engineering medium is used to control the internal environment of each spacer device.

66. The method of claim 36, further comprising the step of analyzing the particles deposited at the one or more simulated drug delivery target regions provided by the mimicked respiratory system, and using the results collected to provide feedback on a particular particle engineering environment.